REMARKS

This Amendment, filed in reply to the Office Action dated October 14, 2009, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 11, 13, 14, 25-27, 30-33, 35 and 37 are rejected. Claim 32 is canceled herewith without prejudice or disclaimer. Claims 11, 33 and 37 are amended herewith. Support for the recitation in Claims 11 and 37 that the "bacterial cells are at least 50% by weight *Methylococcus capsulatus* (Bath) (strain NCIMB 41526) relative to the total bacterial weight" can be found throughout the specification as originally filed, and at, for example, page 2, 5th paragraph, and in original Claim 7. Claim 33 is amended herewith to correct antecedent basis in view of the cancellation of Claim 32.

No new matter is added by way of this amendment. Entry and consideration of this amendment are respectfully requested.

Claims 11, 13, 14, 25-27, 30, 31, 33, 35 and 37 are Patentable Under 35 U.S.C. § 103(a)

On page 3 of the Office Action, the Examiner rejects Claims 11, 13, 14, 25-27, 30-33, 35 and 37 under 35 U.S.C. § 103(a) as allegedly being obvious over Bothe *et al.*, Norferm, DA, Larsen & Joergensen, Atlas & Parks and Patz *et al.*, essentially for reasons of record.

The Examiner continues to take the position that one of ordinary skill in the art, in view of Bothe *et al.*, the Norferm Product Brochure, Larsen *et al.*, Atlas *et al.* and Patz *et al.*, would readily have produced an *autolyzed* biomass from the methanotrophic and heterotrophic bacteria

disclosed by Bothe *et al.*, and would readily have used such biomass as a nutrient source in a bacterial growth medium; motivation for such is alleged to be found in Patz *et al.*, who allegedly establishes that those of ordinary skill in the art at the time of the invention recognized the suitability of using a *hydrolysate* produced from a methanotrophic bacteria as a microorganism growth substrate. On this basis, the Examiner contends that those of ordinary skill in the art would also readily have added a sterile diluent, and glucose (as a carbon source), as additional components of the growth medium.

In response to Applicants' previous arguments and Declaration evidence, the Examiner contends that such are unpersuasive; the Examiner maintains his position that the present claim scope is broader than the unexpected results proffered by Applicants, and that one of ordinary skill in the art would not readily extend the probative value of the data in the specification, or in the Rule 132 Declaration submitted October 8, 2009, to the entire claim scope, for the following reasons.

First, the Examiner appears to believe that Table 1 in the specification as filed depicts experimental results obtained using microorganism growth substrates containing *combinations* of different biomass fractions, rather than growth substrates containing just a single biomass fraction (*e.g.*, BP Extract alone). The Examiner's understanding in this regard appears to stem from the recitation in Example 2 of the specification that the "growth media were produced by adding BP Homogenizate, BP Autolysate, BP Extract, BP Retentate **and** BP Permeate to demineralized water at a concentration of 1g/L." Under this interpretation, the Examiner

concludes that it is unclear what specific biomass fractions, and what amounts thereof, actually produce the unexpected property discovered by Applicants.

Second, the Examiner appears to believe that the unexpected results proffered by Applicants are not commensurate with the scope of Claim 11 because Claim 11 encompasses growth substrates containing *any* amount of "sterilized nutrient composition"; specifically, the Examiner asserts that the Declaration evidence, and the experimental data in the specification, only support an unexpected property using growth medium containing concentrations of between 0.1-4 g/L of biomass.

Third, the rejection appears to be maintained on the basis that Claim 11 does not recite the proportions of each bacterial species in the biomass. The Examiner asserts that the unexpected results proffered in the Declaration are derived from experiments that *only* use biomasses in which the majority of the bacteria are *M. capsulatus*, with minor amounts of the three remaining bacteria. The Examiner appears to believe, that for this reason, the unexpected results are not commensurate with the scope of the claims.

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

First, Applicants respectfully disagree that the experimental data in the specification fails to establish an unexpected property for the claimed autolysates, on the basis that the experiments therein used "combinations" of different biomass fractions. Applicants respectfully point out that those of skill in the art, upon careful reading of the proceeding sections in the specification, would readily understand that each biomass fraction was tested singly, with or without glucose

and nutrient mineral salts. Specifically, those of ordinary skill in the art would readily understand from reading Table 1, and paragraph [0046] of the specification as published, that each biomass fraction was tested individually, and that the referred-to combinations in the specification are combinations of a single biomass fraction with water alone, with water and glucose, or with water, glucose and nutrient mineral salts. Applicants respectfully submit that the Office's interpretation of the experimental protocol in the specification, which is used to maintain the rejection, is entirely at odds with the interpretation that those of ordinary skill in the pertinent art would reach.

Moreover, Applicants respectfully submit that the Declaration evidence of record further demonstrates that biomass fractions, when tested individually, possess superior suitability as broad-spectrum growth media. For example, Applicants' previous Declaration evidence describes the use of BP Extract and BP Autolysate fractions individually, and demonstrates that each possesses superior suitability as broad-spectrum growth media. Nevertheless, even assuming *arguendo* that the Examiner's interpretation of the experimental protocols in the specification were correct, which it is not, Applicants respectfully point out that there is no requirement that data offered to support unexpected properties or results needs to be present in the specification as filed. Evidence presented during *ex parte* prosecution must also be considered.

Second, regarding the Examiner's contention that the claims encompass growth media comprising bacterial biomasses with *any* proportions of the recited bacteria, Applicants respectfully point out that Claims 11 and 37 are amended herewith to recite that the "bacterial

cells are at least 50% by weight *Methylococcus capsulatus* (Bath) (strain NCIMB 41526) relative to the total bacterial weight." Moreover, while the Examiner appears to take the position that the claimed growth substrate encompasses *any* amount of biomass, the Examiner is respectfully reminded that the substrate must nevertheless contain sufficient biomass that it is capable of functioning as a microorganism growth substrate, as claimed.

Third, on page 10 of the Office Action, the Examiner appears to take the position that the experimental data proffered by Applicants only demonstrates an unexpected property for growth substrates produced with the "BP Extract," allegedly because only this extract allowed superior growth of *all* the bacteria tested. However, Applicants respectfully submit that, in asserting such, the Examiner has improperly disregarded Applicants' showing of unexpected properties for at least the "BP Autolysate." As evidenced by the experimental data in the specification as filed, growth media comprising "BP Autolysate" also exhibited superior broad spectrum growth characteristics compared to the control substrate for the majority of the bacteria tested (*i.e.*, for 3 of the 4 tested species). Applicants submit that such evidence is probative of the unexpected properties of growth media containing the "BP Autolysate" fraction. Further, while the Examiner also appears to disregard Applicants' unexpected results because different biomass substrates were allegedly used at different concentrations, Applicants respectfully point out that, because the unexpected effect is evident across these different concentrations, this data merely supports Applicants' position that the unexpected properties are commensurate with claim scope. The pertinent issue is that Applicants used the *same* concentration of the biomass-containing growth medium as that of the relevant control substrate, for each bacteria tested. As such,

Applicants respectfully submit that the results do evidence the superior properties of the claimed substrates compared to those conventionally used in the art (the "control") to provide growth for the tested bacteria.

In view of the Office's misreading of Applicants' experimental data in the specification, and further in view of the claim amendments provided herewith, favorable reconsideration of Applicants' demonstration of unexpected properties is requested.

In addition, and independent of the above, whilst Applicants submit that the evidence of record supporting the unexpected properties of the presently claimed invention is sufficient to rebut even a *prima facie* case of obviousness, Applicants nevertheless maintain that no *prima facie* case has been established, and that the rejection should be withdrawn, for the following reasons.

First, on page 4 of the Office Action, the Examiner acknowledges that neither Bothe *et al.*, Norferm, D, nor Larsen & Joergensen, taken alone or in combination, render obvious a sterile growth substrate comprising a biomass produced by *autolysis* of the bacteria recited in Claim 11 or 37. However, in an attempt to rectify such deficiency, the Examiner cites to Patz *et al.*, who allegedly discloses a chemical thermal hydrolysis step to produce a product that "in the absence of any structural difference recited in the claims, [is] taken as an autolysate," and that such product "can be effectively used as a growth substrate for microorganisms." Applicants, however, respectfully disagree.

Specifically, Applicants respectfully submit that the Examiner's assumption that the hydrolysate of Patz *et al.*, "in the absence of any structural difference recited in the claims, [is]

taken as an autolysate," is flawed. In making such an assertion, the Examiner presumes, without any evidence, that performing the hydrolysis step of Patz *et al.* on the biomass of Bothe *et al.* would produce a product structurally the same as that claimed (*i.e.*, an autolysate). However, Applicants respectfully refer the Examiner to Examples 1 and 2 in the specification as filed, which establish that growth media prepared from hydrolysates of the claimed bacteria demonstrate different bacterial growth profiles vis-à-vis growth media prepared using autolysates, reflecting their very different structures. Thus, biomass fractions produced from the claimed bacteria by hydrolysis and autolysis are both structurally distinct, and nonobvious. Notwithstanding the data in the specification, Applicants respectfully submit that those of ordinary skill in the art would not expect that the hydrolysis conditions of Patz *et al.*, *i.e.*, 150°C at pH 12, would result in a product structurally the same as that produced by autolysis.

Thus, even assuming *arguendo* that one of ordinary skill in the art would have applied the hydrolysis step of Patz *et al.* to the biomass of Bothe *et al.*, they would not have produced the presently claimed "sterilized nutrient composition," nor arrived at the presently claimed invention.

Second, Applicants maintain that the Examiner's proposed combination of the reference disclosures is firmly grounded in impermissible hindsight reconstruction. Even assuming *arguendo* that those of ordinary skill in the art were to consider autolysis, and the hydrolysis step of Patz *et al.*, to produce the same product (which they would not for the above reasons), such does not negate the fact that Patz *et al.* only discloses a biomass produced from *Methylobacterium rhodesianum* IMET 11401 as a substrate for growth of the *very same* bacterial

strain. There is nothing in the art, or in the cited references, that would incite any expectation that a bacterial growth medium comprising a biomass produced from the claimed microorganisms would be effective as a bacterial growth substrate, as the rejection posits. For example, Applicants respectfully refer the Examiner to the results of Examples 1 and 2 of Patz *et al.*, which demonstrates no advantage of supplementing growth medium with bacterial hydrolysate over the use of a defined inorganic nutrient solution and methanol. *See* page 7, Example 2.

Similarly, Applicants respectfully point out that the cited portions of Atlas & Parks pertain principally to media for the growth of microorganisms that *produce* methane; Atlas & Parks neither discloses nor suggests nutrient compositions generated by autolysis of methanotrophic bacteria as presently claimed, which are unexpectedly superior as broad-spectrum growth media.

Moreover, Larsen *et al.* is directed to reducing nucleic acids in *M. capsulatus* through heat shock followed by incubation at an elevated temperature, to enhance suitability for human consumption. Likewise, Bothe *et al.* is directed solely to the use of single cell protein as an animal feedstuff. Thus, like Patz *et al.*, neither Larsen *et al.* nor Bothe *et al.* provide any reason or motivation that would lead those of ordinary skill in the art to use autolysed *M. capsulatus* as a component of a microorganism growth substrate, as the rejection posits. Thus, neither the cited references, nor the art as a whole at the time of the invention, provides any reason or motivation that would have prompted those of ordinary skill in the relevant field to combine the reference

disclosures in the manner asserted in the rejection, as obviousness requires. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

In conclusion, none of the cited documents when taken alone or in combination would result in the invention as presently claimed. In particular, those of ordinary skill in the art would not have possessed sufficient reason or motivation to employ the claimed microorganisms to produce a microorganism growth substrate.

Obviousness-Type Double Patenting

On page 12 of the Office Action, the Examiner *provisionally* rejects Claims 11, 13, 14, 25-27, 30-33, 35 and 37 on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 8, 13-25 and 27 of copending Application No. 10/504,463.

Applicants respectfully submit that the Terminal Disclaimer submitted herewith overcomes the rejection.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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Date: April 14, 2010